IRRIGATION PROBE FOR ABLATION DURING OPEN HEART SURGERY

CROSS-REFERENCE TO RELATED APPLICATION

This application is a divisional of Application Serial No. 09/370,601, filed August 10, 1999, entitled IRRIGATION PROBE FOR ABLATION DURING OPEN HEART SURGERY.

FIELD OF THE INVENTION

Atrial fibrillation is a common sustained cardiac arrythmia and a major cause of stroke. This condition is perpetuated by reentrant wavelets propagating in an abnormal atrial-tissue substrate. Various approaches have been developed to interrupt wavelets, including surgical or catheter-mediated atriotomy. It is believed that to treat atrial fibrillation by radio-frequency ablation using a catheter, continuous linear lesions must be formed to segment the heart tissue. By segmenting the heart tissue, no electrical activity can be transmitted from one segment to another. Preferably, the segments are made too small to be able to sustain the fibrillatory process.

It has been found that over 60% of patients with mitral valve problems also have atrial fibrillation. Moreover, patients undergoing open heart surgery commonly develop atrial fibrillation during the surgery, and thus it would be useful to address this problem during the surgery. Accordingly, under certain circumstances it may be desirable to treat atrial fibrillation during open heart surgery, for example, when a patient is undergoing a mitral valve replacement or repair procedure. Accordingly, a need exists for devices and methods for treating atrial fibrillation during open heart surgery.

SUMMARY OF THE INVENTION

The present invention is directed to an irrigation ablation probe for treating atrial fibrillation during open heart surgery. The probes of the present invention are also useful for other ablation procedures, particularly where irrigation of the ablation site is desired, such as for treating ventricular tachycardia. The invention is also directed to novel methods for treating

atrial fibrillation with the probe of the invention. In accordance with the present invention, the probe comprises a rigid probe body and an irrigated ablation electrode, which provides cooling and irrigation in the region of the tissue being ablated.

In one embodiment, the invention is directed to an irrigation ablation probe comprising a generally rigid probe body having proximal and distal ends. The probe body has an ablation electrode at its distal end having at least one irrigation opening through which fluid can pass. An infusion tube having proximal and distal ends extends through the probe body for introducing fluid into the ablation electrode.

In another embodiment, the invention is directed to an irrigation ablation probe. The probe comprises a generally rigid probe body and a handle. The probe body has proximal and distal ends and comprises an ablation electrode at its distal end. The ablation electrode has at least one irrigation opening through which fluid can pass. The handle is mounted to the proximal end of the probe body, an infusion tube having proximal and distal ends extends through the probe body for introducing fluid into the ablation electrode. In a particularly preferred embodiment, the generally rigid probe body comprises a tubular electrode and a non-conductive sheath covering a portion of the tubular electrode. In another preferred embodiment, the generally rigid probe body comprises tubing having proximal and distal ends and at least one lumen extending therethrough. A tip electrode is mounted at the distal end of the tubing. The tip electrode has at least one irrigation opening through which fluid can pass. The probe body further comprises means for introducing fluid through the irrigation opening(s) of the tip electrode and a stiffening wire extending through a lumen of the tubing. A preferred means for introducing fluid comprises an infusion tube that extends through a lumen of the tubing with the distal end of the infusion tube in fluid communication with the irrigation opening(s) in the tip electrode.

In still another embodiment, the invention is directed to an irrigation ablation probe comprising a generally rigid probe body and a handle mounted to the proximal end of the probe body. The probe body has an ablation electrode at its distal end. The generally rigid probe body comprises a malleable material.

In yet another embodiment, the invention is directed to a method for treating atrial fibrillation in a patient. The method comprises opening the heart of the patient and ablating at least one linear lesion in the heart tissue using an irrigation probe as described above.

DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the present invention will be better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

FIG. 1 is a side view of an embodiment of an irrigation ablation probe according to the invention;

FIG. 2 is a cross-sectional view of the handle of the irrigation ablation probe of FIG.1;

FIG. 3 is perspective view of the distal end of the irrigation ablation probe of FIG.1;

FIG. 4 is a side view of an alternative embodiment of an irrigation ablation probe according to the invention;

FIG. 5 is a side cross-sectional schematic view of the distal end of the irrigation ablation probe of FIG. 4, wherein the lumens are not shown to scale; and

FIG. 6 is an end cross-sectional view of the distal end of the irrigation probe of FIG. 4.

DETAILED DESCRIPTION

The present invention is directed to an irrigation ablation probe for use during open heart surgery. In one embodiment, as shown in FIGs. 1 and 2, the irrigation ablation probe **10** comprises a probe body **12** mounted to a handle **14**. The probe body **12** comprises a tubular electrode **16**, having proximal and distal ends, covered over a proximal portion of its length by a non-conductive covering or sheath **18**. The tubular electrode **16** extends the entire length of the probe body **12**, the proximal end of the tubular electrode extending into the handle **14** as described in more detail below. The probe body **12** preferably has a length (from the distal end of the handle to the distal end of the probe body) ranging from about 3.5 inches to about 12 inches, more preferably from about 5 to about 10 inches, still more preferably from about 7 to about 8 inches.

The tubular electrode **16** is made of a material that is generally rigid so that the probe body **12** cannot bend during ablation, such as, for example, stainless steel (preferably 304VSS) or nitinol. Preferably the tubular electrode **16** has an inner diameter ranging from about 0.40 inches to about 0.80 inches, more preferably about 0.047 inches, and an outer diameter ranging from about 0.50 inches to about 0.90 inches, more preferably about 0.059 inches. If desired, the tubular electrode **16** can be heat-treated so that it is malleable enough to be bent by a physician to a desired shape but still rigid enough that is will not end in use during an ablation procedure. For example, for 304VSS stainless steel, the material is heated to about 800°F with electrical current or in a salt bath. The hollow interior of the tubular electrode **16** forms a lumen through which saline and the like may be infused during an ablation procedure, as described in more detail below.

The non-conductive sheath **18** extends from a proximal end inside the handle **14** to a distal end that is longitudinally spaced apart from the distal end of the tubular electrode **16**. In this arrangement, the distal end of the tubular electrode **16** is exposed, i.e., not covered by the sheath **18**, for ablating tissue. Preferably, the length of the exposed portion of the tubular electrode **16** ranges from about 0.50 inches to about 1.5 inches, more preferably from about 0.75 inches to about 1.25 inches. The sheath **18** can be made of any suitable biocompatible non-conductive material, such as polyurethane.

In the embodiment depicted in FIGs. 1 to 3, the probe body **12** is bent near its distal ends at an a angle α, with the exposed distal end of the tubular electrode **16** being generally straight. However, the probe body **12** can alternatively be straight along its entire length. The angle α preferably ranges from about 0° to about 270°, more preferably from about 60° to about 140°, still more preferably about 90°. The angle α depends on the location of the heart tissue to be ablated. If the tubular electrode **16** is malleable, the surgeon can bend the probe body **12** to adjust the angle α for particular procedure.

In the depicted embodiment, the length of the probe body **12** is approximately 7 inches. The proximal section of the probe body **12**, i.e., the portion extending from the handle **14**, is approximately 5.5 inches. The length of the exposed distal portion of the tubular electrode **16**, i.e., the portion not covered by the sheath **18**, is approximately 1 inch.

As shown in FIG. 3, the exposed distal end of the tubular electrode **16** has a series of irrigation openings **20** for passage of a cooling fluid out through the electrode. The irrigation openings **20** can take any suitable shape, such as rectangular or oval slots or round holes. The irrigation openings **20** are preferably in the section of the exposed portion of the tubular electrode **16** that is to be in contact with the tissue during an ablation procedure to enhance the cooling of the ablation site.

Saline or other suitable fluid is introduced into the tubular electrode **16** through a luer hub **22** or the like at the proximal end of the probe **10**. The luer hub **22** is connected to a flexible plastic tubing **24**, e.g., made of polyimide. The plastic tubing **24** is attached to the proximal end of the tubular electrode **16**, preferably within the handle **14**, as shown in FIG. 2. Alternatively, the tubing **24** can be connected to a suction source (not shown) to permit aspiration of fluid from the region being ablated.

As shown in FIG. 2, the handle **14** comprises a housing **26** having a generally open interior **28**. the tubular electrode **16** and sheath **18** extend into the distal end of the handle housing **26**. In the depicted embodiment, the sheath **18** terminates a short distance proximal to the distal end of the housing **26**. The tubular electrode **16** continues proximally beyond the sheath **18**. The flexible plastic tubing **24** extends into the proximal end of the handle housing **26**. The plastic tubing **24** is attached to the tubular electrode **16** within the open interior **28** of the handle, preferably at a point proximal to the proximal end of the sheath **18**. The plastic tubing **24** can be attached to the tubular electrode **16** by any suitable means, for example, polyurethane glue. By this design, cooling fluid is introduced through the luer hub **22**, through the plastic tubing **24**, through the tubular electrode **16** and out the irrigation openings **20** in the exposed distal end of the tubular electrode.

An electrode lead wire **30** having proximal and distal ends is electrically connected at or adjacent its distal en to the tubular electrode **16**. The proximal end of the lead wire **30** is attached to a connector **32** for connection to a suitable source of radio frequency energy. In the depicted embodiment, the lead wire **30** extends into the proximal end of the handle housing **26**. within the open interior **28** of the handle **14**, the distal end of the lead wire **30** is wrapped around the portion of the tubular electrode **16** not covered by the sheath **18** and held in place by solder or the like.

The portion of the lead wire **30** that extends outside the handle **14** is covered by a flexible plastic protective tubing **34**, e.g., made of polyimide.

An alternative embodiment of an irrigation ablation probe according to the invention is shown in FIGs. 4 to 6. The probe **10** comprises a probe body **12** and a handle **14**. The probe body **12** comprises a non-conductive tubing **40** having proximal and distal ends. Ina particularly preferred embodiment, the non-conductive tubing **40** comprises outer and inner plastic walls, e.g., of polyurethane or polyimide, surrounding an imbedded braided mesh of stainless steel or the like. Preferably, the tubing has an outer diameter of less than 8 French, more preferably less than 7 French. The tubing **40** has three lumens **42, 44** and **46** extending along its length.

An irrigated tip electrode **48** is fixedly mounted on the distal end of the non-conductive tubing **40**. Preferably, the tip electrode **48** has a diameter about the same as the outer diameter of the tubing **40** and an exposed length, i.e., the length extending outside of the tubing, ranging from about 2 mm to about 10 mm. as illustrated in FIG. 5, the tip electrode **48** is generally solid, having a fluid passage **50** and first and second blind holes **52** and **54** that correspond in size and location to the three lumens **46, 42** and **44**, respectively, in the non-conductive tubing **40**. In the embodiment shown, the fluid passage **50** comprises a longitudinal branch **56** and six transverse branches **58** that extend transversely from near the distal end of the longitudinal branch to the outer surface of the tip electrode **48**. It is understood that the configuration of the fluid passage **50** may vary as desired. For example, the fluid passage **50** may form a longitudinal hole that extends our the distal end of the tip electrode **48** without transverse branches, or the tip electrode **48** may be porous enough to allow fluids to pas to the outer surface of the tip electrode, the interconnecting pores forming the fluid passage. Examples of suitable porous electrodes for use in the present invention are described in U.S. Patent application entitled "Porous Irrigated Tip Electrode Catheter," by inventors Michele Fung and Shawn Moaddeb, filed concurrently herewith, the disclosure of which is incorporated herein by reference.

The tip electrode **48** can be attached to the non-conductive tubing **40** in any suitable manner. In the depicted embodiment, the tip electrode **48** is attached to the tubing **40** by polyurethane glue or the like. The wires or tubes that extend into the tip electrode **48**, discussed more below, help to keep the tip electrode in place on the tubing **40**. However, any other means for fixedly mounting the tip electrode **48** on the distal end of the tubing **40** can also be used.

In the embodiment shown, a mapping ring electrode **62** is mounted on the tubing **40** proximal to the tip electrode **48**. It is understood that the presence and number of ring electrodes may vary as desired. The ring electrode **62** is slid over the tubing **40** and fixed in place by glue or the like.

The tip electrode **48** and ring electrode **62** can be made of any suitable material, and are preferably machined from platinum-iridium bar (90% platinum/10% iridium).

The tip electrode **48** and ring electrode **62** are each connected to a separate lead wire **64**. the lead wires **64** extend through the first lumen **42** or tubing **40** and through the handle **14**. the lead wires **64** terminate at their proximal ends in a connector **32** that may be plugged into an appropriate monitor and/or source of radio frequency energy. The portion of the lead wires **64** extending out the proximal end of the handle **14** are enclosed within a protective tubing **34**, which can be made of any suitable material, preferably polyimide.

The lead wires **64** are attached to the tip electrode **48** and ring electrode **62** by any conventional technique. Connection of a led wire **64** to the tip electrode **48** is accomplished, for example, by soldering the lead wire **64** into the second blind hole **54** in the tip electrode.

Connection of a lead wire **64** to the ring electrode **62** is preferably accomplished by first making a small hole through the tubing**40**. Such a hole can be created, for example, by inserting a needle through the tubing **40** and heating the needle sufficiently to form a permanent hole. A lead wire **64** is then drawn through the hold by using a microhook or the like. The ends of the lead wire **64** are stripped of any coating and soldered or welded to the underside of the ring electrode **62**, which is then slid into position over the hold and fixed in place with polyurethane glue or the like.

A temperature sensing means is provided for the tip electrode **48** and, if desired, the ring electrode **62**. Any conventional temperature sensing means, e.g., a thermocouple or thermistor, may be used. With reference to FIG. 5, a preferred sensing means for the tip electrode **48** comprises a thermocouple formed by a wire pair. One wire of the pair is a copper wire **66**, e.g., a number 38 copper wire. The other wire of the wire pair is a constantan wire **68**, which gives support and strength to the wire pair. The wires **66** and **68** of the wire pair are electrically isolated from each other except at their distal ends where they contact and are twisted together, covered with a short piece of plastic tubing **70**, e.g., polyimide, and covered with epoxy. The

plastic tubing **70** is then attached in the first blind hole **52** of the tip electrode **48** by polyurethane glue or the like. The wires **66** and **68** extend through the first lumen **42** in the non-conductive tubing **40**. the wires **66** and **68** then extend out through the handle **14** and to a connector (not shown) connectable to a temperature monitor (not shown).

Alternatively, the temperature sensing means may be a thermistor. A suitable thermistor for use in the present invention is Model No. AB6N2-GC14KA143E/37C sold by Thermometrics (New Jersey).

An infusion tube **72** is provided for infusing fluids, e.g., saline, to cool the tip electrode **48**. the infusion tube **72** may also be used to infuse drugs or to collect tissue or fluid samples. The infusion tube **72** may be made of any suitable material, and is preferably made of polyimide tubing. The infusion tube **72** has proximal and distal ends, with its distal end mounted in the fluid passage **50** of the tip electrode **48** by any suitable method, e.g., by polyurethane glue or the like. The infusions tube **72** extends from the tip electrode **48**, through the third lumen **46** of the tubing **40**, and through the handle **14**. The proximal end of the infusion tube **72** ends in a luer hub **22** or the like.

A stiffening wire **74**, having proximal and distal ends, is mounted in the second lumen **44** of the tubing **40**. The stiffening wire **74** is made of a rigid metal or plastic material, preferably stainless steel, to prevent the probe body **12** from bending during an ablation procedure. If desired, the stiffening wire **74** can be heat-treated so that it is malleable and can be bent to a desired shape before use, but still rigid enough that it will not end in use during an ablation procedure. A non-conductive tube **76**, preferably made of polyimide, is attached to the distal end of the stiffening wire **74** for mounting the stiffening wire in the tip electrode **48**. the non-conductive tube **76** extends out of the second lumen **44** and into the second blind hole **54** in the tip electrode **48**, and is secured in place by polyurethane glue or the like. The non-conductive tube **76**, along with the infusion tube **72**, lead wires **64**, and thermocouple wires **66** and **68**, helps to maintain the tip electrode **48** in place on the tubing **40**. As would be recognized by one skilled in the art, the stiffening wire **74** could be mounted in any other suitable way so long as the stiffening wire, if made of metal, is not in electrical connection with the tip electrode **48**. the proximal end of the stiffening wire **74** terminates in the handle **14** or near the proximal end of the probe body **12**.

The tubular electrode **38** is then used to form continuous linear lesions by ablation. As used herein, a linear lesion refers to any lesion, whether curved or straight, between two anatomical structures in the heart that is sufficient to block a wavelet, i.e., forms a boundary for the wavelet. Anatomical structures, referred to as "atrial trigger spots," are those regions in the heart having limited or no electrical conductivity and are described in Haissaguerre et al., "Spontaneous Initiation of Atrial Fibrillation by Ectopic Beats Originating in the Pulmonary Veins," New England Journal of Medicine, 339:65-666 (Sept. 3, 1998), the disclosure of which is incorporated herein by reference. The linear lesions typically have a length of from about 1 cm to about 4 cm, but can be longer or shorter as necessary for a particular procedure.

The above described probes are for use during open heart surgery. During a procedure, the heart is opened and the irrigated electrode is used to form continuous linear lesions by ablation. the above-described probe having a long tubular electrode is particularly useful for this procedure because it can create relatively long lesions. The probe depicted in FIGs. 4 to 6, having a smaller ablation electrode, is useful if the surgeon does not want to ablate as much tissue or wants to ablate a more precise lesion. The above-described probe having a malleable body is particularly useful if the surgeon needs to bend the probe to better ablate a desired region of tissue. Once the heart is closed, the surgeon can use the probe depicted in FIGs. 4 to 6 on the outside of the heart, not only to ablate, but to verify that the electrical conduction has been stopped using the mapping electrodes. As would be recognized by one skilled in the art, the probes of the present invention can be used during open heart surgery for other ablation procedures as well.

The preceding description has been presented with reference to presently preferred embodiments of the invention. Workers skilled in the art and technology to which this invention pertains will appreciate that alterations and changes in the described structure may be practiced without meaningfully departing from the principal, spirit and scope of this invention.

Accordingly, the foregoing description should not be read as pertaining only to the precise structures described and illustrated in the accompanying drawings, but rather should be read consistent with and as support for the following claims which are to have their fullest and fairest scope.